

QA: QA

**U. S. DEPARTMENT OF ENERGY  
OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT  
OFFICE OF QUALITY ASSURANCE**

**AUDIT REPORT LLNL-ARC-99-08**

**OF**

**LAWRENCE LIVERMORE NATIONAL LABORATORY**

**AT**

**LIVERMORE, CALIFORNIA**

**SEPTEMBER 13 - 17, 1999**

**Prepared by:** \_\_\_\_\_ **Date:** \_\_\_\_\_

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Office of Quality Assurance**

**Approved by:** \_\_\_\_\_ **Date:** \_\_\_\_\_

**Robert W. Clark  
Acting Director  
Office of Quality Assurance**

## **1.0 EXECUTIVE SUMMARY**

This Quality Assurance (QA) Compliance Audit was conducted at the Lawrence Livermore National Laboratory (LLNL), Livermore, California, on September 13-17, 1999, to evaluate QA Program elements directly related to LLNL work activities for compliance to the Quality Assurance Requirements Document (QARD) and implementing procedures at the LLNL.

The audit team determined that LLNL is satisfactorily and effectively implementing the Office of Civilian Radioactive Waste Management (OCRWM) QA Program in accordance with the U.S. Department of Energy (DOE) OCRWM QARD document, DOE/RW-0333P, Revision 8, and the LLNL's implementing procedures.

QA Program elements 1.0, 2.0, 4.0, 5.0, 7.0, 12.0, 15.0, 16.0, Supplements I, II, III, and Appendix C are effectively implemented. QA Program elements 6.0 and 17.0 are not effectively implemented as detailed in Section 5.4 of this report. The QA element regarding Supplement V was not audited due to the continuation of corrective actions under Deficiency Report (DR) LVMO-98-D-055. Currently, elements 3.0, 8.0, 9.0, 10.0, 11.0, 13.0, 14.0, 18.0, and Supplement IV are not implemented by LLNL.

As a result of the audit, identified conditions adverse to quality resulted in the issuance of five DRs and are addressed in Section 5.4.2 of this report. In addition, there were two deficient conditions corrected during the audit requiring only remedial actions, as addressed in Section 5.4.3 of this report. Three recommendations are identified for LLNL management consideration, as addressed in Section 6.0 of this report.

The audit team reviewed four open and seven closed deficiency documents identified during previous OCRWM Office of Quality Assurance (OQA) audits and surveillances to determine the status of in-process and effectiveness of completed corrective actions by LLNL. Corrective actions were found to be effective; however, in one case, the effectiveness of corrective actions revealed a new instance of a condition adverse to quality as addressed in Section 5.4.4 of this report.

## **2.0 SCOPE**

Auditors representing the OCRWM OQA conducted a compliance audit to evaluate the LLNL's implementation of the OCRWM QA Program as described in the QARD and implementing procedures at the LLNL facilities.

In addition, the audit team reviewed the status of open and closed OCRWM deficiency documents identified during previous OQA audits and surveillances to determine the effectiveness of in-process and completed corrective actions by LLNL.

The audit team conducted interviews and reviews of documentation to evaluate the

adequacy, compliance, and effectiveness of implementation of the OCRWM QA Program at LLNL.

In accordance with the approved audit plan, the following QA Program elements were evaluated:

**QA Program Elements**

1.0	Organization
2.0	QA Program
4.0	Procurement Document Control
5.0	Implementing Documents
6.0	Document Control
7.0	Control of Purchased Items and Services
12.0	Control of Measuring and Test Equipment
15.0	Nonconformances
16.0	Corrective Action
17.0	QA Records
Supp I	Software
Supp II	Sample Control
Supp III	Scientific Investigation
Appendix C	Mined Geologic Disposal System

The following QA program elements were not reviewed during the audit, since LLNL is not currently implementing them:

3.0	Design Control
8.0	Identification and Control of Items
9.0	Control of Special Processes
10.0	Inspection
11.0	Test Control
13.0	Handling, Storage, and Shipping
14.0	Inspection, Test and Operating Status
18.0	Audits
Supp IV	Field Surveying
Appendix A	High-Level Waste form Production
Appendix B	Storage and Transportation

**3.0 AUDIT TEAM MEMBERS / OBSERVERS**

The following is a list of audit team members and their assigned areas of responsibility:

<b><u>Name/Title/Organization</u></b>	<b><u>QA Program Elements</u></b>
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Michael A. Goyda, Audit Team Leader, OQA	1.0, 2.0, 16.0, Supplements III and V
Kristi A. Hodges, Auditor, OQA	4.0, 7.0, 12.0, Supplement I and Appendix C
Victor J. Barish, Auditor, OQA	2.0, 5.0, and 6.0
Mario R. Diaz, Auditor, OQA	17.0, Supplements II and III
F. Harvey Dove, Auditor, OQA	2.0, and Supplement III
Edward P. Opelski, Auditor, OQA	15.0
Jack Spraul, Observer, Nuclear Regulatory Commission (NRC)	
Tom Trbovich, Observer, NRC	
Albert Williams, Observer, DOE	

#### **4.0 AUDIT TEAM MEETINGS AND PERSONNEL CONTACTED**

A pre-audit meeting was conducted at LLNL on Monday, 09/13/99. Daily debriefings were held to apprise LLNL management and staff of the progress of the audit and any identified conditions adverse to quality. A post-audit meeting was conducted at LLNL on Friday, 09/17/99.

Attachment 1, "Personnel Contacted During the Audit," includes those personnel that attended the pre-audit and post-audit meetings.

#### **5.0 SUMMARY OF RESULTS**

##### **5.1 Program Effectiveness**

The audit team concluded that, for the QA Program elements examined through the audit, LLNL has effectively implemented the QA Program for the scope of this audit with the exceptions noted in Section 5.4 of this report.

The results for each QA Program element evaluated are contained in Attachment 2, Summary Table of Audit Results.

##### **5.2 Stop Work or Immediate Corrective Action Taken**

There were no Stop Work Orders, or immediate corrective actions taken as a result of the audit.

##### **5.3 QA Program Implementation**

Attachment 2, "Summary Table of Audit Results," provides results for each QA

Program element audited. Details of the audit, including the objective evidence reviewed, are documented in the audit checklist. The checklist is maintained as a QA record.

#### **5.4 Summary of Conditions Adverse to Quality**

The audit team identified deficient conditions adverse to quality during the audit that resulted in issuance of five DRs as discussed in Section 5.4.2 of this report. In addition, two deficiencies identified during the audit which required only remedial actions were corrected during the audit as addressed in Section 5.4.3 of this report.

##### **5.4.1 Corrective Action Request (CAR)**

None

##### **5.4.2 Deficiency Reports (DR)**

###### **DR LLNL-00-D-002**

Contrary to the requirement of LLNL Quality Procedure 033-YMP-QP-2.1, Revision 8, "Preparation, Approval and Revision of Procedures, Requirements, and Plans," Paragraph 2.1.5.4.1, LLNL provided no objective evidence that the OCRWM OQA Representative reviewed and concurred with the RTN/QARD matrix mark-ups for new and revised procedures.

###### **DR LLNL-00-D-003**

Part A - Contrary to the requirement of YMP Administrative Procedure, AP-2.13Q, Revision 0, "Technical Product Development and Planning," Paragraph 5.2.e 2, LLNL failed to place the QA designator (QA/QA) on five Development Plans.

Part B - LLNL's failure to properly place QA designators on the five Development Plans indicates ineffective retraining of personnel as a corrective action to previously issued and closed DR LLNL-98-D-090 regarding the similar placement of QA designators on LLNL generated documents.

###### **DR LLNL-00-D-004**

Part A - Contrary to the requirement of LLNL Quality Procedure 033-

YMP-QP 6.0, Revision 5, CN 5-5, "Document Control," Paragraph 6.0.5.5.2, the LLNL YMP Controlled Document Server did not match the approved hard copy documents. Remedial action to revise 033-YMP-QP 6.0 to require an independent review of documents loaded into the LLNL YMP Document Control Server was completed prior to the audit closeout meeting.

Part B - Contrary to the requirement of LLNL Quality Procedure 033-YMP-QP 2.1, Revision 8, CN N/A, "Preparation, Approval, and Revision of Procedures, Requirements, and Plans," Paragraph 2.1.5.6, LLNL controlled documents did not reference revision information on each page.

#### **DR LLNL-00-D-005**

Part A - Contrary to the requirement of YMP Administrative Procedure, AP-17.1Q, Revision 1, "Record Source Responsibilities for Inclusionary Records," Paragraph 5.3.d, LLNL QA records that have been previously submitted to the RPC have been corrected and re-transmitted to RPC without reflecting the accession number of the original record that was being corrected.

Part B - Contrary to the requirement of YMP Administrative Procedure, AP-17.1Q, Revision 1, "Record Source Responsibilities for Inclusionary Records," Paragraph 5.3.2. 1) and 3), LLNL QA records have been corrected without noting the initials or date by the person making the correction.

#### **DR LLNL-00-D-006**

Contrary to the requirement of the QARD, Revision 8, Section 5.2.2, LLNL TIPs reflect requirements for the conduct of periodic surveillances that are no longer performed due to organizational structure changes. The TIPs do not reflect the current performance of work activities.

### **5.4.3 Deficiencies Corrected During the Audit (CDA)**

Deficiencies considered isolated in nature and only requiring remedial action can be corrected during the audit. The following deficiencies were identified and corrected during the audit:

#### **CDA 1**

LLNL, 033-YMP-QP-1.0, Revision 5, Change Notice (CN) 5-3, "Organization" depicted a Business Manager position that was no longer applicable to LLNL.

This condition was corrected during the audit by the LLNL Laboratory Lead by issuance of CN 5-4 to the procedure that served to remove the Business Manager position from the procedure and organization chart.

## **CDA 2**

NCR YMSCO-99-0060 contained the serial number of a Mettler balance that was different than the serial number found on the balance itself. This condition was corrected during the audit by the LLNL OQA representative who made a proper correction on the record and a copy of the NCR. The NCR was sent to the LLNL records coordinator for submittal to the RPC.

### **5.4.4 Follow-up of Previously Issued Deficiency Documents**

Follow-up of LLNL corrective actions relative to DR LLNL-98-D-007 regarding development of an Activity Plan for the Drift Scale Test and DR LLNL-98-D-093 regarding compliance of Scientific Notebooks were evaluated during the audit. Both DR's were related to the documentation of activities and planning conducted in Scientific Notebooks. As a result, comprehensive reviews of Scientific Notebooks have been completed at LLNL. Both DR's were satisfactorily resolved, verified and closed by OQA (DR LLNL-98-D-007 closed 09/22/99 and DR LLNL-98-D-093 closed 06/10/99). No new instances of these conditions were identified during the audit.

Follow-up of DR LLNL-98-D-065 was performed during the audit. The DR identified that LLNL did not qualify the NUFT Software per the QARD requirements. This DR was satisfactorily resolved, verified and closed by the OQA on 09/21/99. No new instances of this condition were identified during this audit.

Follow-up of DR LLNL-98-D-087 revealed that this DR has been closed by OQA on 08/06/99 and the corrective actions were incorporated into corrective actions associated with the CAR LVMO-99-C-001 issued to the CRWMS M&O.

Follow-up of the DR LLNL-98-D-088 was performed during the audit. The DR identified that LLNL had not submitted lists of cited references to the YMP RPC. The action to preclude recurrence for this DR was superseded by a revision to the controlling procedure AP-17.1Q, Revision 1, "Record Source Responsibilities for Inclusionary Records," that deleted the requirement for the submittal of cited references to the RPC. This DR was satisfactorily resolved, verified and closed by the OQA on 11/30/98. No new instances of this condition were identified during the audit.

Follow-up of DR LLNL-98-D-089 was performed during the audit. The DR identified that LLNL did not incorporate manufacturer's manuals into TIPs as required. The audit team verified no recurrence of this condition. This DR was satisfactorily resolved, verified and closed by the OQA on 12/16/98. No new instances of these conditions were identified during this audit.

Follow-up of LLNL corrective actions relative to DR LLNL-98-D-090 regarding documentation of indexing information on each record such as; traceability designators, QA designators, author's name and organization was evaluated during the audit. This DR was satisfactorily resolved, verified and closed by OQA on 12/31/98; however, in the case of the new DR LLNL-00-D-003 regarding failure of LLNL to place QA designators on the identified Development Plans, the corrective actions taken to correct this condition were ineffective. This condition is addressed in DR LLNL-00-D-003 that was issued as a result of this audit.

Follow-up of DR LLNL-98-D-091 was performed during the audit. The DR identified that LLNL did not properly control labeling of M&TE, LLNL used NCR's to evaluate out of tolerance M&TE, and LLNL failed to identify procedures used to perform calibrations. This DR was satisfactorily resolved, verified and closed by the OQA on 12/06/98. No new instances of these conditions were identified during this audit.

Follow-up of DR LLNL-98-D-092 was performed during the audit. The DR identified that LLNL procurements are not completed in accordance with the controlling procedure. As verified during this audit, LLNL no longer performs "Q" procurements as this activity is managed through the CRWMS M&O. This DR was satisfactorily resolved, verified and closed by the OQA on 10/14/99. No new instances of this condition were identified during this audit.

Follow-up of DR LLNL-98-D-094 was performed during the audit. The DR identified several deficient conditions related to the content of the LLNL Activity Plans. This DR was satisfactorily resolved, verified and closed by the OQA on 06/02/99 and planning is now controlled by AP-2.13Q, Revision 0, "Technical Product Development Planning," and AP-2.15Q, Revision 0, "Work Package Planning Summaries." No new instances of this condition were identified during this audit.

The audit team completed follow-up and the verification of DR LLNL-99-D-068 regarding the planning of work activities supporting conduct of Electrical Resistivity Tomography testing at the YMP Busted Butte. As a



result of the verification during this audit, this DR was recommended for closure and the DR was closed by OQA on 10/07/99. No new instances of this condition were identified during the audit.

## **6.0 RECOMMENDATIONS**

The audit team identified three recommendations as a result of the audit that are presented for LLNL Management's consideration.

1. To preclude NCRs from remaining open until lengthy tests are completed, it is recommended that justification memos, in accordance with YAP-12.3Q, Revision 0, "Control of Measuring and Test Equipment and Calibration Standards," be written for non-retrievable M&TE that are beyond established calibration intervals.
2. A review of all LLNL TIPs should be completed to assure content requirements are in accordance with the recently issued YAP-12.3Q, Revision 0, "Control of Measuring and Test Equipment and Calibration Standards."
3. LLNL should place emphasis during any Scientific Notebook reviews to increase the personnel awareness of editorial compliance.

## **7.0 LIST OF ATTACHMENTS**

Attachment 1: Personnel Contacted During the Audit  
Attachment 2: Summary Table of Audit Results

## ATTACHMENT 1

### Personnel Contacted During the Audit

<u>Name</u>	<u>Organization/Title</u>	<u>Pre-Audit Meeting</u>	<u>Contacted During Audit</u>	<u>Post-Audit Meeting</u>
Barbara Alegre	LLNL, Records Coordinator	X	X	
Mike Belanger	LLNL, Engineering Assurance Support	X	X	X
Stephen Blair	LLNL, Principal Investigator	X	X	
Thomas Buscheck	LLNL, Senior Scientist	X		
Barbara Campbell	LLNL, Code Qualification Manager	X	X	X
Bill Clarke	LLNL, Technical Area Leader	X	X	
Mike Coatsworth	LLNL, Technical Data Coordinator	X	X	X
Earlene Cruz	LLNL, Secretary Assistant		X	
John Estill	LLNL, Laboratory Supervisor	X	X	
Joe Farmer	LLNL, Senior Scientist		X	
Gregory Gdowski	LLNL, Principal Investigator	X		
Tom Gibson	LLNL, Technical Reviewer		X	X
Joanne Horn	LLNL, Principal Investigator	X	X	
Edward Kansa	LLNL, Physicist	X		
Ken King	LLNL, Senior Chemical Technician	X		
Martha Kohler	LLNL, Laboratory Lead	X	X	X
Tiangan Lian	LLNL, Metallurgist	X	X	
Wunan Lin	LLNL, Technical Area Leader	X	X	X
Al Lingenfelter	LLNL, Principal Investigator	X		X
Daniel McCright	LLNL, Deputy Technical Area Leader	X	X	X
Holly Miller	LLNL, Analyst			X
Royce Monks	LLNL, Engineering Assurance Manager	X	X	X
William O'Connell	LLNL, Engineer	X		
Cynthia Palmer	LLNL, Deputy Laboratory Lead		X	X
Jeane Palmer	LLNL, Administrative Specialist		X	
Greg Parent	LLNL, Technical Data Compiler		X	X
Karen Queheilalt	LLNL, YMP Administration			X

<u>Name</u>	<u>Organization/Title</u>	<u>Pre-Audit Meeting</u>	<u>Contacted During Audit</u>	<u>Post-Audit Meeting</u>
Tanya Reshel	LLNL, QA Administration	X	X	
Nina Rosenberg	LLNL, Senior Technical Staff		X	
Ajit Roy	LLNL, Advisory Engineer	X		
Edward Russell	LLNL, Senior Technical Staff		X	
Jack Spraul	Nuclear Regulatory Commission Observer	X	X	X
Pam Stanworth	LLNL, Training Coordinator		X	
Steve Steward	LLNL, Deputy Technical Area Leader	X		
Ray Stout	LLNL, Technical Area Leader	X		X
Tammy Summers	LLNL, Principal Investigator	X	X	
Tom Trbovich	Nuclear Regulatory Commission Observer	X	X	X
Charles Warren	LLNL, On-Site OQA Representative	X	X	X
Robert Wemheuer	CRWMS M&O, NEPO Manager	X		X
Albert Williams	DOE OQA	X	X	X

**ATTACHMENT 2**  
**Summary Table of Audit Results**

<b>DETAIL SUMMARY</b>								
<b>QA PROGRAM ELEMENT</b>	<b>IMPLEMENTING DOCUMENTS</b>	<b>DETAILS ( ) LIST</b>	<b>DEFICIENCY REPORTS</b>	<b>CDA's</b>	<b>RECOM's</b>	<b>PROGRAM ADEQUACY</b>	<b>PROCEDURE COMPLIANCE</b>	<b>OVERALL</b>
Organization	QP 01.0, R. 5, CN 5-3	Pgs. 1 & 2	N/A	#1	N/A	SAT	SAT	SAT
QA Program	QARD, 2.2.12, R 8	Pg. 3	N/A	N/A	N/A	SAT	SAT	SAT
	QARD, 2.2.1, R 8	Pgs. 4 & 5	LLNL-00-D-002	N/A	N/A	SAT	UNSAT	
	AP-2.1Q, R 0	Pgs. 6 & 7	N/A	N/A	N/A	SAT	SAT	
	QP 2.10, R 5, CN 5-5	Pgs. 8 & 9	N/A	N/A	N/A	SAT	SAT	
	AP-2.2Q, R 0	Pgs. 10 & 11	N/A	N/A	N/A	SAT	SAT	
	QARD, 2.2.9, R 8	Pg. 12	N/A	N/A	N/A	SAT	N/I	
	AP-2.12Q, R 0	Pg. 12	N/A	N/A	N/A	SAT	N/I	
	AP-2.13Q, R 0	Pgs. 13 - 15	LLNL-00-D-003	N/A	N/A	SAT	UNSAT	
Procurement Document Control	QP 04.0, R 6, CN 6-4	Pgs. 16 & 17	N/A	N/A	N/A	SAT	SAT	SAT
Implementing Documents	QP 5.0, R 4, CN 4-3	Pgs. 22 – 25 & 29a	N/A	N/A	N/A	SAT	SAT	SAT
	QP 2.1, R 8,	Pgs. 26 - 28	N/A	N/A	N/A	SAT	SAT	
	AP-5.2Q, R 0, ICN 0	Pg. 29	N/A	N/A	N/A	SAT	N/I	
Document Control	QP 6.0, R 5, CN 6.0-5.5	Pgs. 30 - 32	LLNL-00-D-004	N/A	N/A	SAT	UNSAT	UNSAT
	AP-6.1Q, R 3, ICN 0	Pgs. 33 & 34	N/A	N/A	N/A	SAT	N/I	
Control of Purchased Items & Services & QARD Appendix C	QP 7.0, R 2, CN 2-3	Pgs. 18	N/A	N/A	N/A	SAT	SAT	SAT
	AP-7.4Q, R 0, ICN 0	Pgs. 19 - 21	N/A	N/A	N/A	SAT	SAT	
Control of M & TE	YAP-12.3Q, R 0	Pgs. 35 – 43a	N/A	N/A	#1 & 2	SAT	SAT	SAT

DETAIL SUMMARY								
QA PROGRAM ELEMENT	IMPLEMENTING DOCUMENTS	DETAILS ( ) LIST	DEFICIENCY REPORTS	CDAs	RECOMs	PROGRAM ADEQUACY	PROCEDURE COMPLIANCE	OVERALL
Control of Non-Conformances	YAP-15.1Q, R 4	Pgs. 44 - 50	N/A	N/A	N/A	SAT	SAT	SAT
Corrective Actions	AP-16.1Q, R 4	Pgs. 51 – 53 & 56	N/A	N/A	N/A	SAT	SAT	SAT
	AP-16.2Q, R 3	Pg. 54	N/A	N/A	N/A	SAT	N/I	SAT
	AP-16.4Q, R 0	Pg. 55	N/A	N/A	N/A	SAT	N/I	SAT
Records	AP-17.1Q, R 1	Pgs. 57 - 60	LLNL-00-D-005	#2	#3	SAT	UNSAT	UNSAT
Supplement I Software	AP-SI.1Q, R 1	Pgs. 61 - 71	N/A	N/A		SAT	SAT	SAT
Supplement II Sample Control	QP 8.0, R 2, CN 2-2	Pgs. 72 - 74	N/A	N/A	N/A	SAT	SAT	SAT
	TIP-CM-18, R 0	Pg. 75	LLNL-00-D-006	N/A	N/A	SAT	UNSAT	
	TIP-CM-02, R 0	Pgs. 76 & 77	LLNL-00-D-006	N/A	N/A	SAT	UNSAT	
	TIP-CM-01, R 0	Pgs. 78 & 79	LLNL-00-D-006	N/A	N/A	SAT	UNSAT	
Supplement III Scientific Investigations	QP 2.4, R 1, CN 1-1	Pgs. 80 & 81	N/A	N/A	N/A	SAT	SAT	SAT
	AP-2.14Q, R 0	Pg. 82	N/A	N/A	N/A	SAT	SAT	
	YMP-QAP-3.15, R 0	Pgs. 83 & 84	N/A	N/A	N/A	SAT	N/I	
	AP-3.10Q, R 1	Pgs. 85 - 89	N/A	N/A	N/A	SAT	SAT	
	AP-3.11Q, R 0	Pgs. 90 & 91	N/A	N/A	N/A	SAT	SAT	
	AP-3.15Q, R 0	Pgs. 92 & 93	N/A	N/A	N/A	SAT	SAT	
	AP-SIII.2Q, R 0	Pg. .94	N/A	N/A	N/A	SAT	SAT	

DETAIL SUMMARY								
QA PROGRAM ELEMENT	IMPLEMENTING DOCUMENTS	DETAILS ( ) LIST	DEFICIENCY REPORTS	CDAs	RECOMs	PROGRAM ADEQUACY	PROCEDURE COMPLIANCE	OVERALL
Supplement III Scientific Investigations	AP-SIII.3Q, R 0	Pg. 95	N/A	N/A	N/A	SAT	SAT	SAT
	AP-3.14Q, R 0	Pgs. 96 & 97	N/A	N/A	N/A	SAT	N/I	
	AP-SIII.1Q, R 0	Pg. 98	N/A	N/A	N/A	SAT	SAT	
	QP 3.4, R 4	Pgs. 99 - 106	N/A	N/A	N/A	SAT	SAT	
Supplement V Control of Electronic Management of Data	QP 3.8, R 0	Pg. 107	N/A	N/A	N/A	Not Audited	Not Audited	Not Audited
<b>TOTAL</b>		Pages 107	5 DRs	2	3			

**LEGEND:**

CDAs ..... Corrected During Audit

RECOMs ..... Recommendations

ADEQUACY ..... Procedures Contain Requirements

Overall ..... Summary of Element

NA ..... Not Applicable

SAT ..... Satisfies Criteria

NI ..... No Implementation